

Remarks

Claims 1-35 are pending and stand rejected. Claims 1-35 under 35 U.S.C. 103 as being obvious over U.S. Patent No. 5,183,040 to Nappholz ("the Nappholz patent"). The Applicants traverse the rejections for the reasons stated below.

The Office Action stated that Nappholz teaches the use of ultrasound for measuring the cardiac output of the heart, placing an ultrasound catheter in the heart to generate acoustic signals, and attaching an electrode to the desired position. The Office Action also stated that although Nappholz fails to mention that ultrasound could be used for imaging, U.S. Patent No. 6,120,453 to Sharp ("the Sharp patent") teaches that element. Furthermore, the Office Action stated it would have been obvious to modify Nappholz's ultrasound catheter system such that it could be used for imaging purposes according to the teachings of Sharp so that accurate placement of the electrode could be made. The Applicants disagree with these assertions for the reasons stated below.

A new therapy has been recently introduced that re-synchronizes the heart. This involves pacing the left ventricle of the heart in conjunction with the right ventricle. However, in order for this to be successfully accomplished, the placement of the pacing electrode within the heart must be optimized and must be extremely precise. In addition, during this new procedure, knowledge of the volumetric output of the heart is also highly desirable.

Amended claim 1 recites "an ultrasound imaging catheter designed for intracardiac use." The catheter gathers ultrasound signals and processes the ultrasound signals "in order to simultaneously measure the cardiac output in the patient's heart and display an image of the area of the patient's heart."

In contrast, Nappholz teaches the use of a pacer device that employs a Doppler sensor and that is implanted within one of the chambers of the heart. Nappholz patent, col. 4, lines 57-63. More specifically, Nappholz notes that "[t]he pacer ensonifies blood with ultrasonic waves, processes returning echoes to extract the audio portion of Doppler ultrasound signals, and analyzes the signals to quantify the cardiac output of the

heart.” Nappholz patent, Col. 5, lines 40-44. The pacer device described by Nappholz does not capture images of the heart and no images are displayed to users.

Nappholz does not contemplate the new procedure described above. As mentioned in Nappholz, Nappholz “relates to implantable medical devices which monitor and control a patient’s hemodynamic state by measuring cardiac output from the left ventricle of the heart.” Nappholz, col. 1, lines 12-14. In other words, there is nothing in Nappholz that suggests a need for the exact placement of electrodes as required by the new procedure mentioned above. Further, there is no suggestion in Nappholz of a procedure that both optimizes electrode placement and uses volumetric outflow data to advance the procedure.

Sharp teaches the use of two ultrasound probes to determine three-dimensional image of the heart. Sharp patent, Col. 4, lines 31-52. However, the Sharp reference notes that “[t]he primary application of this technology, as presently perceived, is to use an internal transesophageal and an external transabdominal probe to image the heart and nearby structures.” Consequently, although the Sharp technology can be applied to other body structures, the size of the probes that would be applied to these body structures remains large.

It is believed that the proposed combination of Nappholz and Sharp is improper because there is no teaching, suggestion, or motivation in either of the references for the proposed combination. As mentioned, Nappholz is concerned with determining a flow rate of the heart. Nappholz did not contemplate the new procedure outlined above that requires the exact placement of electrodes and, therefore, would have no need for imaging any probe to determine an exact placement. Consequently, no motivation exists to add ultrasound imaging to a system that is concerned with measuring the volumetric outflow of the heart. The Applicants have identified the previously unrecognized problems associated with the new procedure and addressed these problems as claimed. Absent a reason to combine the references, it is believed that the Office Action has improperly parsed through the teachings of the prior art to individually locate the claimed elements and then combined them as claimed by the Applicants.

Furthermore, it is also believed the proposed combination is improper since the Sharp reference inherently teaches against the suggested modification. Specifically, Sharp is large device that is placed down the esophagus of a patient. Because Sharp is positioned relatively far from the heart and has bone and tissue between it and the heart, the Sharp device must employ high frequencies, not the low frequencies as used by the Applicants' system. The Applicants noted this distinction in their application, specifically stating that their approach "employs lower frequencies (e.g., about 5 and about 10 MHz)" as compared to previous systems such as Sharp. Specification, page 6, lines 13-14. In other words, the Sharp system could not and would not function properly at low frequencies. Consequently, Sharp inherently teaches against adjusting the frequency as suggested by the Office Action and, therefore, it is believed that it is improper to combine these references for this additional reason.

Claim 11 recites "advancing the electrode to the proximity of the upper left ventricle" and placing an ultrasound imaging catheter in a position to image the left ventricle of the patient's heart. In contrast, as outlined above with respect to claim 1, there is nothing in Nappholz that teaches or suggests that an electrode can be guided to the proximity of the upper left ventricle and precisely placed using the procedure that is recited in the claim. Sharp is only concerned with imaging objects, not guiding electrodes as claimed by the Applicants. Since a claimed element is not taught or suggested by either of the references, it is believed that claim 11 is allowable.

Amended claim 25 recites "an ultrasound imaging catheter designed for intracardiac use comprising a multi-element array." In contrast, the arrays used in the references appear to be single element arrays. There is nothing to suggest that multi-element arrays could or should be used in either of the references. Since an element of claim 25 is not taught or suggested by the references, it is believed that claim 25 is allowable.

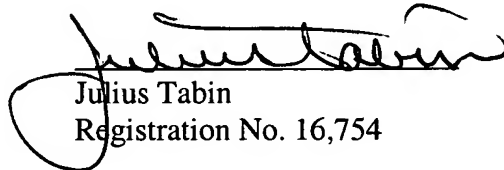
The remaining claims depend directly or indirectly upon the above mentioned independent claims. Since the above-mentioned independent claims are allowable, it is believed that the remaining claims are allowable for the reasons stated above.

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The Commissioner is hereby authorized to charge any additional fees which may be required in this application to Deposit Account No. 06-1135.

Respectfully submitted,

Fitch, Even, Tabin & Flannery



Julius Tabin
Registration No. 16,754

Date:

120 South LaSalle Street, Suite 1600
Chicago, Illinois 60603
Telephone: (312) 577-7000
Fax No.: (312) 577-7007